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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,393	12/21/2001	Stephen Quirk	11301-1170 (44039-250928)	1033

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EXAMINER	
SWOPE, SHERIDAN	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 07/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/026,393	QUIRK ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-45 is/are pending in the application.

4a) Of the above claim(s) 1-17 and 26-45 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 18-25 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 0202;0402;0103.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-45 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-17, drawn to a signal element-containing apparatus for detection of a proteinase.

Group II, claim(s) 18-25, drawn to a method for detection of a proteinase using the apparatus of Group I.

Group III, claims 26-30, drawn to a method for treating chronic wounds using the apparatus of Group I.

Group IV, claims 31-38, drawn to a apparatus for detection of a proteinase.

Group V, claim(s) 39-42, drawn to a method for detection of a proteinase using the apparatus of Group IV.

Group VI, claims 43-45, drawn to a method for treating chronic wounds using the apparatus of Group IV.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: The technical feature linking Groups I-VI appears to be that they all relate to detection of a protease. However, Englert et al, 2000 teach a method for detection of a protease (Fig 2D). Therefore, Groups I-VI share no special technical feature, as defined by PCT Rule 13.2, as the shared technical feature does not define a contribution over the

prior art. Furthermore, the apparati of Groups I and IV use different steps, while the methods of Groups II and III and the methods of Groups V and VI can be performed using products other that the apparati of Groups I and IV, respectively. Accordingly, Groups I-VI are not so linked as to form a single general inventive concept.

During a telephone conversation with Jason Johnston on June 22, 2004 a provisional election was made without traverse to prosecute Invention II, Claims 18-25. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-17 and 26-45 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification-Objections

Oath

The Oath/Declaration is objected to because the Inventor's name has been changed from Tyrell to Tyrrell without an initialing or dating of the change. A new Oath/Declaration is required.

Abstract

The Abstract is objected to for poor grammar. For example, the first sentence is a run-on sentence. Correction is required.

Figures & Figure Legends

The figures and figure legends are objected to. The figure legends should define all labeling in the figures. For example, in figure 1, numbers 1-4 and 13 should be defined. For each figure, the numbers should be defined in the figure legend. Correction is required.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 18, it is unclear whether the signal element is bound to the target antibody. Claims 19-25, as dependent on Claim 18 are rejected for the same reasons. Clarification is required. For purposes of examination, and based on the teachings of the specification, it is assumed that the signal element is bound, either directly or indirectly, to the target antibody.

Claim Rejections - 35 USC §

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18-22, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Sorsa et al, 1998 (IDS). Sorsa et al teach a method for detecting the matrix metalloproteinase-8 (MMP-8), which uses an immunochromatographic lateral flow technique. A first antibody to

MMP-8 is coated onto particles and acts a label that can be detected, for example by its fluorescent or chemiluminescent properties. A sample of an oral swab from an individual having periodontal disease is applied to a reservoir of a capillary support/membrane system. The label/antibody/particles, which are applied to the membrane, migrate by diffusion coming in contact with and binding any MMP-8 in the sample. Further diffusion of the label/antibody/particle/MMP-8 complex brings the complex into contact with a second antibody that has been attached in a zone-like area of the membrane. When the liquid flow, carrying the complex migrates through this zone, label/antibody/particle complexes that have bound antigen are bound to the zone. Thus, the zone is detectable if MMP-8 is present in the sample (Abstract; col 22, lines 19-45). Therefore, Claims 18-22, 24, and 25 rejected under 35 U.S.C. 102(b) as being anticipated by Sorsa et al, 1998.

Claims 18-21, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Golub et al, 2000 (IDS). Golub et al teach (Abstract; col 22, lines 25-52) a method for detecting the matrix metalloproteinase-13 (MMP-13), which uses the same technology described in Sorsa et al, 1998. Therefore, Claims 18-21, 24, and 25 rejected under 35 U.S.C. 102(b) as being anticipated by Golub et al, 1998.

Claims 18, 19, 21, 22, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Maliszewska et al, 2001 (IDS). Maliszewska et al teach a method for detecting matrix metalloproteinase-9 (MMP-9) in human cerebrospinal fluid using a monoclonal antibody to MMP-9 as a capture antibody and a polyclonal antibody, with an associated signal element, as a detector antibody. Maliszewska et al further teach that their method is useful for detecting

MMP-9 in inflammatory neurological conditions, such as trauma. Therefore, Claims 18, 19, 21, 22, 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Maliszewska et al, 2001.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maliszewska et al, 2001 in view of Sorsa et al, 1998. The teachings of Maliszewska al are described above. Maliszewska et al do not teach a method wherein the target antibody and signal element are attached to a particle or wherein the signal element is a colorimetric compound, a radio-active compound, a potentiometric element, a fluorescent compound, a chemo-illuminescent coumpound, a light diffracting element, or a combination thereof. As described above, Sorsa et al teach a method for detecting a protease, wherein the antibody and signal element are attached to a particle and the signal element is a fluorescent or chemiluminescent compound. It would have been obvious to a person of ordinary skill in the art to use the techniques of Sorsa et al to improve on the method of Maliszewska et al. Motivation to do so is provided by the fact that the technique of Sorsa et al does not require an enzymatic reaction to detect the protease, which is advantage over the method of Maliszewska et al. Motivation to combine is also provided by the need to compare MMP-9 levels in normal individuals with those having an inflammatory neurological disorder, for example in response to trauma, as taught by Maliszewska et al. The expectation of success is high, as measuring the

levels of MMPs in human samples is known in the art; for example, as taught by Sorsa et al, 1998 and Golub et al, 2000. Therefore, Claims 20, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maliszewska et al, 2001 in view of Sorsa et al, 1998.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sorsa et al, 1998 in view of Rowe et al, 1999 and further in view of Vu et al, 2000. The teachings of Sorsa et al are described above. Sorsa et al does not teach a method for detecting a plurality of proteinases in a sample. Rowe et al teach a method for detecting a plurality of proteins in a mixed sample using an array of capture antibodies specific for three different proteins. After incubation with the mixed sample, the binding of each specific protein to its respective capture antibody is detected by a fluorescently-labeled target antibody, which binds to the same specific protein. In this manner, the presence of each of a plurality of proteins in a mixed sample is detected (Fig 4). It would have been obvious to a person of ordinary skill in the art to incorporate the array technique of Rowe et al into the methods of Sorsa et al. In such a combined method, an array of capture antibodies to a plurality of proteases would be used to bind a plurality of proteases in a mixed sample, which would be detected using fluorescent or chemiluminescent target antibodies to the proteases. Motivation to do so is derived from the fact that proteases are involved in a plethora of normal and abnormal human conditions (Vu et al, 1999) and that the array would allow efficient determination of which proteases are present in patient samples. The expectation of success is high, as both the use of capture-antibody arrays to detect a plurality of proteins and the use of capture antibodies to detect proteases are known in the art. Therefore, Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sorsa et al, 1998 in view of Rowe et al, 1999 and further in view of Vu et al, 2000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan Lee Swope, Ph.D.

REBECCA E. PRUTY
PRIMARY EXAMINER
GROUP ~~1800~~
1600